REMARKS

Sequence Alignment

Applicants thank the Examiner for faxing a copy of the sequence alignments of SEQ ID NO: 1 of the present application with the sequence of AC074365 and with the sequence of BF242113, on June 14, 2004.

Status of the Claims

Claims 72-87 are pending in the present application. Claims 1-71 have been canceled without prejudice or disclaimer of the subject matter claimed therein. New claims 72-87 have been added.

Amendments to the Claims

New claims 72-87 have been added to more clearly define the claimed invention and do not include prohibited new matter. New claims 72-87 replace claims 1-5, 23-29, and 49. Support for new claims is summarized in the table below.

TABLE

Claims	Support
72	Claim 1; paragraph 0010; paragraph 0068
73	Claim 1
74	Claims 1 and 2
75-78	Claims 3-5
79	Claim 1
80	Claim 23
81	Claim 25

82	Claim 24
83	Claim 26
84	Claim 27
85	Claim 28
86	Claim 29
87	Claim 49

Priority Date of SEQ ID NO: 1 and 2 of the Present Application

Applicants respectfully point out that SEQ ID NO: 1 and SEQ ID NO: 2 of the present application were disclosed as SEQ ID NO: 1 and SEQ ID NO: 2, respectively, in U.S. Provisional Application 60/251,835, filed on December 8, 2000. Accordingly, new claims 72-87 (which replaced claims 1-5, 23-29, and 49), directed in part to SEQ ID NO: 1 and SEQ ID NO: 2 and currently under examination, should be accorded the benefit of priority of December 8, 2000, *i.e.* the filing date of U.S. Provisional Application 60/251,835.

Rejections of the Claims Under 35 U.S.C. § 112, First Paragraph

A. Claims 1, 3, 5, 23-29 and 49 are rejected under 35 U.S.C. § 112, first paragraph, purportedly because the specification is only enabling for an isolated nucleic acid molecule comprising SEQ ID NO: 1 encoding the amino acid sequence of SEQ ID NO: 2.

The Office Action alleges that the specification does not enable the breadth of the claims without undue experimentation. Moreover, the Office Action cites the *Wands* factors for consideration as to what is undue experimentation.

Regarding the scope of the invention, claims 1, 3, 5, 23-29 and 49 have been canceled and replaced with new claims 72-87. New claims 72-87 are directed to nucleic acid molecules that hybridize under stringent conditions to the complement of a nucleic acid encoding SEQ ID NO: 2 and encode a protein that is differentially expressed in activated mast cells. Claims 72-87 only encompass nucleic acid molecules that meet both of these

limitations. The claims do not encompass an unlimited variety of nucleic acid molecules, and the claims provide both structural and functional limitations that are described and enabled by the specification.

Regarding the nature of the invention and state of the prior art, hybridization techniques under stringent conditions were well known to the skilled artisan at the time the application was filed. Moreover, the specification adequately describes hybridization under stringent conditions in paragraph 0068 of the specification. The specification discloses SEQ ID NO: 2 and the nucleic acid encoding SEQ ID NO: 2. In the Examples, specifically Examples 1, 2, and 5, the specification discloses isolation and cloning of the MC1 clone comprising SEQ ID NO: 2. Given this information and the state of the art, it does not require undue experimentation to obtain nucleic acids that hybridize under stringent conditions to the complement of the nucleic acid encoding SEQ ID NO: 2 and that encode a protein that is differentially expressed in activated mast cell.

With regards to unpredictability of the invention, the Office Action states that changes in protein and nucleic acid sequences are unpredictable based on the cited references Ngo *et al.*, Skolnick *et al.*, Attwood *et al.* and Wallace *et al.* The cited references have been considered, but are not applicable to the present case because the claimed invention encompasses only those nucleic acid sequences that meet the limitations of the claims. The claims require that the nucleic acid molecules hybridize to the complement of SEQ ID NO: 2 under stringent conditions and encode a protein that is differentially expressed in activated mast cells. As discussed above, hybridization techniques under stringent conditions were well known at the time the application was filed. The specification, specifically Examples 1, 2, and 5, provides guidance for isolating nucleic acids encoding proteins that are differentially expressed in an activated mast cell. Accordingly, the claimed invention is not unpredictable.

Ex parte Aggarwal and *In re Wands* have been considered. However, since the invention is not unreasonably claimed and not unpredictable as discussed above, the cited cases are not relevant.

Regarding the number of working examples and amount of guidance, the specification provides sufficient guidance to enable one to practice the claimed invention.

The specification, specifically Examples 1, 2, and 5, teaches how to isolate nucleic acids encoding proteins that are differentially expressed in activated mast cells. Paragraphs 00165 to 00176 and 00206 to 00209 of Examples 1, 2, and 5 describe MC1 in detail. In paragraph 0068, the specification describes in detail hybridization under stringent conditions. Accordingly, the specification provides an adequate amount of guidance and working examples for practicing the claimed invention. It would not require undue experimentation to obtain the nucleic acids encompassed by the claims.

Regarding the limitation of "35 % sequence identity" in claim 79, Applicants respectfully point out that the claims also require that the nucleic acid molecule hybridizes to the complement of a nucleic acid encoding SEQ ID NO: 2 under stringent conditions and encodes a protein differentially expressed in mast cells activated through the IgE receptor. Thus, the specification provides sufficient guidance and example to enable the limitation of claim 79.

In summary, given the teachings of the specification and the state of the art in the area of hybridization of nucleic acids, it would not require undue experimentation for one of ordinary skill in the art to make and/or use the claimed invention.

B. Claims 1, 3, 23-29, and 49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 23-29, and 49 have been canceled and replaced with claims 72-87. Claims 72-86 are directed to nucleic acid molecules encoding a protein differentially expressed in mast cells activated through the IgE receptor and hybridizing under stringent conditions to a complement of a nucleic acid molecule encoding SEQ ID NO: 2. Therefore, the claims only encompass nucleic acid molecules that meet both of these limitations. Applicants also point out that claim 79 which includes the limitation that the protein exhibits at least about 35 % sequence identity to SEQ ID NO: 2, is dependent from claim 72.

The specification adequately describes the nucleic acid molecules encompassed by claim 72 and the dependent claims. As an example, paragraphs 00165-00176 and 00206-

00209 describe the claimed invention in detail. Paragraph 0065 provides examples of the nucleic acids of the present invention, and paragraphs 00165-00176 provide guidance for the isolation of the nucleic acids of the present invention. Moreover, paragraph 0068 describes hybridization under high stringency conditions. Accordingly, the specification provides a description of the required structure of the claimed nucleic acids.

The Office Action cites *University of California v. Eli Lilly* to support their rejection. Applicants respectfully point out that the *Eli Lilly* is not relevant in this case because unlike the claims in *Eli Lilly,* the claims in the present application do not encompass a broad genus of undefined nucleic acids. The claims of the present application only encompass nucleic acids that hybridize under stringent conditions to a nucleic acid encoding SEQ ID NO: 2 and encode a protein differentially expressed in mast cells activated though the IgE receptor.

The Office Action also cites *Rochester v. G.D. Searle.* However, *Searle* is not relevant to the present application because the present specification discloses nucleic acids encompassed by the claims. Unlike the specification of *Searle* which did not identify any compounds that can be used in the claimed method of treatment, the instant specification adequately describes the nucleic acids encompassed by the claims.

Regarding the Guidelines for Written Description Requirement, Applicants respectfully point out that Example 9 of the *Revised Interim Written Description Guidelines Training Materials* (1999) discloses a claim with hybridization language. The claim was found to be adequately described when the specification discloses a single species, SEQ ID NO: 1. The reason is that the claim sets forth the hybridization conditions, and one of skill in the art would not expect substantial variation among species encompassed within the scope of the claims. Likewise, claim 72 of the present application includes the limitation that the nucleic acid molecules must hybridize under stringent conditions to the complement of a nucleic acid molecule encoding SEQ ID NO: 2 thereby limiting variation among the nucleic acid molecules encompassed within the scope of the claims.

Applicants also point the Examiner to the recent decision from the Board of Patent Appeals and Interferences, Appeal No. 2002-2046 (see attached). The decision clearly states that the structure of a claim using the phrase "comprising" in the context of a disclosed sequence does not amount to a lack of written description for failure to describe "additional

nucleic acids at either or both ends" as stated by the Examiner on page 4 of the Office Action. (See pages 25 and 26 of the decision.)

Respectfully, the specification has adequately described the claimed invention and applicants request withdrawal of this rejection.

Rejections of the Claims Under 35 U.S.C. § 112, Second Paragraph

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been canceled and replaced with claim 72. Claim 72 includes a specific hybridization condition. Accordingly, the rejection is moot.

Rejections of the Claims Under 35 U.S.C. § 102

As discussed above, this application should be accorded the benefit of priority of December 8, 2000, *i.e.*, the filing date of U.S. Provisional Application 60/251,835.

A. Claim 1 is rejected under 35 U.S.C. § 102(a) as being anticipated by Waterston *et al.* (Accession No. AC074365, Sept. 2000).

Claim 1 has been canceled and replaced with claim 72. Claim 72 is directed to nucleic acid molecules encoding a protein differentially expressed in mast cells activated through the IgE receptor and hybridizing under stringent conditions to a complement of a nucleic acid molecule encoding SEQ ID NO: 2. The nucleic acid encoding SEQ ID NO: 2 is over 3700 nucleotides in length. Waterston *et al.* do not disclose a nucleic acid that hybridizes under stringent conditions to the complement encoding SEQ ID NO: 2 and encodes a protein differentially expressed in mast cells activated through the IgE receptor. The nucleic acid clone of Waterston *et al.* is a genomic clone consisting of 141,268 nucleotides. This genomic clone only comprises nucleotides encoding amino acids 56 to 135 of SEQ ID NO: 2. Accordingly, the nucleic acid clone of Waterston *et al.* does not meet the limitations of claim 1 and therefore does not anticipate claim 1. Applicants respectfully request withdrawal of the rejection.

B. Claims 3 and 5 are rejected under 35 U.S.C. § 102(a) as being anticipated by Accession No. BF242113 (Strausberg, Nov. 14, 2000).

The Office Action indicates that the date of the cited reference is November 14, 2000. However, Applicants respectfully point out that the date on the cited reference is November 16, 2004.

Claims 3 and 5 have been canceled and replaced with claims 76 and 78. Attached is a Declaration under 37 C.F.R. 1.131 executed by the inventors establishing invention of the claimed subject matter in this country prior to November 14, 2000. Although Applicants only need to establish invention prior to November 16, 2000, Applicants are able to establish invention of the claimed subject matter prior to November 14, 2000. The data exhibited in the slides of Exhibit A attached to the Declaration were obtained by the inventors herein prior to November 14, 2000. Accordingly, the cited reference does not anticipate claims 3 and 5. Applicants respectfully request withdrawal of the rejection.

Applicants have submitted a Declaration under 37 C.F.R. 1.131 executed by only one inventor, since the other two inventors could not be reached at this time. Applicants are aware that all three inventors must sign the Declaration. A copy of the Declaration executed by all three inventors will be forwarded to the Patent Office as soon as the other two inventors execute the Declaration. If the Examiner considers this response prior to the submission of the other two signatures, Applicants request consideration of the declaration on its merits.

C. Claims 1, 23-29, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Dalton *et al.* (Accession No. M85165, 1992).

Claims 1, 23-29, and 49 have been replaced with claims 72-87. Claim 72 is directed to nucleic acid molecules encoding a protein differentially expressed in mast cells activated through the IgE receptor and hybridizing under stringent conditions to a complement of a nucleic acid molecule encoding SEQ ID NO: 2. Claims 73-87 depend from claim 72.

Dalton *et al.* do not disclose a nucleic acid that will hybridize under stringent conditions to the complement of a nucleic acid encoding SEQ ID NO: 2 and that encodes a protein differentially expressed in mast cells activated through the IgE receptor. The only

portion of the nucleic acid of Dalton *et al.* that is identical or even similar to the nucleic acid encoding SEQ ID NO: 2 is the poly A tail at the 3' end of the nucleic acid. Accordingly, the nucleic acid of Dalton *et al.* does not meet the limitations of the claim and therefore does not anticipate the claimed invention. Applicants respectfully request withdrawal of the rejection.

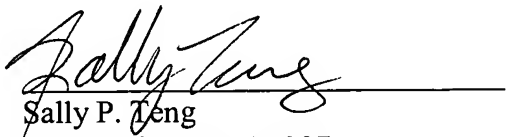
Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, they are invited to telephone the undersigned at their convenience.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which my be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. 1.136(a)(3).

Respectfully submitted,
Morgan, Lewis & Bockius LLP



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